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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,705	02/11/2002	Dean Hughes	HO-P02368US0	4397

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/073,705

Applicant(s)

HUGHES ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/11/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 1 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The abstract of the disclosure is objected to because of the use of the abbreviation "UHMWPE." This must be spelled out to avoid confusion. Appropriate correction is required.

The disclosure is objected to because of the following informalities.

The first occurrence of the abbreviation "UHMWPE" (page 4, para 0014, line 5) must be accompanied by the expansion to avoid confusion.

On page 6, para 0025, line 6 and line 9: tibial insert "36" and tibial platform "36" have the same numbering. Appropriate correction is required.

On page 8, para 0034, line 4, "100" should be "101" to be consistent with the drawings.

The specification is objected to as failing to provide proper antecedent basis for the subject matter of claims 5 and 13. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

### ***Claim Objections***

Claims 1 and 10 are objected to because of the following informalities.

In claim 1, line 9: "component" (second occurrence) should be "insert" to be consistent with the disclosure. Appropriate correction is required.

In claim 10, line 2: - - "of the patient"- - must be inserted after "in the body" for clarity. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394).

Regarding claims 1-4, 6-7, 11-12, 14-17 and 19-20, Afriat et al. disclose a knee joint prosthesis having a femoral component 1 with two condylar portions (5a, 5a), a cam 9 extending between the posterior portions of the condylar portions, a tibial component 2 configured to be implanted into a patient's tibia, and a tibial insert 3 having a proximal surface shaped to articulate against femoral component 1 wherein the distal surface of tibial insert 3 fits against the proximal surface of tibial component 2 and a central projecting rib or post 30 on the tibial insert 3 engages intercondylar cage or box 8 of femoral component 1 for posterior stabilization (Figure 1, col. 4, lines 19-67, col. 5, lines 4-9 and lines 16-19).

Afriat et al. do not disclose a diffusion-hardened surface or coating on a portion of the cam for adding strength and wear resistance to the contact zones of the cam.

Davidson teaches diffusion-bonded or "diffusion-hardened" coating of load bearing and non-load bearing surfaces of implants such as a knee joint prosthesis with blue-black or black zirconium oxide (col. 1, lines 14-35; col. 5, lines 11-26 and lines 47-55; col. 6, lines 51-68; and col. 7, lines 1-11 and lines 36-48).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a diffusion-hardened coating on a load-bearing contact surface of the knee joint prosthesis of Afriat et al. to minimize wear and reduce friction or a non-load bearing surface to minimize corrosion of the prosthesis as taught by Davidson.

Davidson does not specifically disclose diffusion-hardened coating of a cam surface (load-bearing surface) or the inner side of parallel vertical walls connected to the inner sides of posterior condylar portions (non-load bearing surface) of a femoral component of a knee joint prosthesis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided diffusion-hardened coating in specific locations of the knee joint prosthesis of Afriat et al., since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 7.

Regarding claims 5 and 13, Davidson teaches coatings of variable thickness (col. 8, lines 7-9 and lines 22-40; and col. 10, lines 18-21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a thicker coating on a load bearing surface (greater wear) than a non load bearing surface (lesser wear), since it has been

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held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 8 and 9, Afriat et al. disclose that the tibial insert 3 is made of material such as high-density or "ultra-high molecular weight" polyethylene to enable sliding of femoral component 1 against tibial insert 3. Further, the use of ultra high molecular weight polyethylene tibial inserts is well known in the art (see Davidson, col. 4, lines 27-29).

Regarding claim 10, Afriat et al. disclose a prosthesis body 3 for implantation in the body of a patient wherein the load bearing surface 25 of the prosthesis body 3 is sized and shaped to engage with a second load bearing surface on another prosthesis portion 1 and a non-load bearing surface 30 on the prosthesis body 3 is sized and shaped to cooperate with a second non-load bearing surface 8 on another prosthesis portion 1 (Figure 1, col. 4, lines 20-67 and col. 5, lines 4-19). The load bearing surface 25 and the non-load bearing surface 30 are formed of an organic polymer (col. 4, lines 59-60).

Regarding claim 18, although Afriat et al. do not disclose a cam shaped as a horizontal bar but Afriat et al. disclose rollback of femoral component 1 on tibial insert 3 by the presence of constrained box 8. It would have been obvious to one of ordinary skill in the art to have provided a cam shaped as a horizontal bar since it has been held that mere changes in shape are a matter of obvious design choice absent any persuasive evidence that the particular shape or configuration is significant.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR

March 5, 2003

  
PEDRO PHILOGENE  
PRIMARY EXAMINER